MR 48677

BASF Corporation 8EHQ-0601-14641S

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June 4, 2001

8EHQ-00-14641
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Document Processing Center (TS-790)
Attention: 8(e) Coordinator
Office of Pollution and Toxics
U. S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

COMPANY SANITIZED

Ladies and Gentlemen:

Subject: Supplementary Information to EPA Document Number 8EHQ-00-14641: Results of the Evaluation of the Fetal Skeletons in a Full-Scale Prenatal Developmental Toxicity Study in Himalayan Rabbits with a Nitrogen Heterocycle

Supplementary to the information provided with EPA Document Number 8EHQ-00-14641, BASF Corporation is submitting additional results of a prenatal developmental toxicity study in Himalayan rabbits with an experimental herbicide a Nitrogen Heterocycle conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany.

The study was carried out in accordance with the requirements of the following guidelines:

- EC Commission Directive 87/302/EEC of November 18, 1987, Official Journal of the European Communities, No. L 133 (1988).
- OECD Guidelines for Testing of Chemicals, Proposal for Updating Guideline 414, Prenatal Developmental Toxicity (Draft Document August 1999).
- EPA, Health Effects Test Guidelines; OPPTS 870.3700: Prenatal Developmental Toxicity Study (August 1998).
- Japan/MAFF: Testing Guidelines for Toxicology Studies: Teratogenicity Study (1985).

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The test substance was administered by gavage to 25 pregnant female Himalayan rabbits/group at doses of 0, 50, 150 and 450 mg/kg body weight on day 7 through day 28 post insemination. At scheduled necropsy, 22 - 25 females/group had live fetuses. The evaluation of the fetal skeletons was performed without knowledge of treatment group.

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Washington, DC 20460

The following is a summary of the most relevant skeletal findings:

Although not always clearly dose related, increased incidences of supernumerary thoracic vertebrae and supernumerary ribs as well as sternebral changes like incompletely ossified or unossified sternebrae were observed at all dose levels. These findings are considered as skeletal variations because they also appear spontaneously. At the high dose level, clear signs of maternal toxicity were observed.

Please note that a sanitized version of this letter is enclosed, treating the chemical identity as confidential business information. The confidential chemical name is referred to as "Nitrogen Heterocycle". An up-to-date confidentiality substantiation letter is already on file for this product (8EHQ-00-14641).

Sincerely,

BASF CORPORATION

Edward J. Kerfoot /mk

Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations

mk
Enc.